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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/051,383	01/22/2002	Indra Sandal	056859-0137	6958

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EXAMINER	
HELMER, GEORGIA L	

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 03/11/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/051,383	SANDAL ET AL.	
	Examiner	Art Unit	
	Georgia L. Helmer	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-25 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-25 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

1. Claims 1-25 are pending and are examined in the instant action.

Specification

2. The specification and claims are objected to as being unduly narrative. Literature citations in the claims are improper. Literature citations properly belong in a PTO form 1449. Any amendment to the specification should avoid the introduction of new matter.

Claim Rejections - 35 USC § 112-2nd

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-25 are rejected under 35 USC § 112-2 for the following reasons:

Claim 1 is an improper method claim since the final step of the method does not result in the production of the desired product, namely transgenic tea.

In claim 1,

- (r), line 1, "the leaf explants " lacks antecedent basis.
- (r), line 3, it is ambiguous whether "alone" refers only to mannitol, or to the three other sugars also.
- (r), line 6, "like" is unclear because it is a relative terms for which no comparative basis is given. Furthermore, it is unclear whether the

terms recited after "like" are required or merely exemplary. All subsequent recitations of this terminology are also rejected.

- (t), "the regeneration medium" lacks antecedent basis

(u), Claim 1 contains the trademark/trade name BioRad (u), Eppendorf (x), DuPont (bb). Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe the sauce of microprojectiles or test tubes, and, accordingly, the identification/description is indefinite. All subsequent recitations of this term are also rejected.

- In claim I (v), "the gold particles" lacks antecedent basis. Also, what does "each" refer to?
- In I (x) "dispension" is unclear since this term is not found in the dictionary. Is "dispersing" an appropriate term?
- In 1 (y) line 3, "simultaneous vortexing from time to time" is contradictory. It is either simultaneous or from time to time.
- (y) line 5, "washing" what? "final suspension" of what?

- 1(z), where did the "suspension" come from? does it result from step (y)?
- In I (bb) line 1 "with" should be replaced by "using" for clarity.
- In I (cc) "each plate" of what?
- In I (dd) "the bombarded explants" lacks antecedent basis. Explants of "somatic embryos, zygotic embryos and embryogenic calli" lack antecedent basis.
- In I (ee), "culturing" what? a temperature of "25+2 degree C" is 27 degrees. Should this be "25+/-2 degrees? what does "of culture lab" mean?
- In I (ff) line 3, "the transformed leaf explant" lacks antecedent basis.
- In I (gg), line 1, "after two days" is unclear—is this in addition to the two days of step (ff)?
- In I (hh) line 1, "after every 15 days on selection" lacks antecedent basis—no selection. Also, what it is t=0 for the 15 days?
- In (hh) line 2, what does the "(r) " mean?
- In (hh) line 2, "regeneration of shoot buds" is an additional step and should be properly indicated by a separate step number designation and indentation.
- In (hh) lines 3-4, the "3 to 5 months old in vitro raised cultures" lacks antecedent basis.

- In (hh) lines 7, what does the "(s) " mean? "growing and multiplying" is an additional step and should be properly indicated by a separate step number designation and indentation.
- In (hh) line 7, "the transformed shoots" lacks antecedent basis .
- In (hh) line 9, what does the "(t)" mean? "molecular characterization" is an additional step and should be properly indicated by a separate step number designation and indentation. Also, since this is the last step of the method, the preceding step should end with a comma followed by "and".

Claims 1 is further indefinite in the recitation in the preamble of "novel combination", which implies that the claim is a product claim. However claim 1 is drawn to the method. Furthermore, "novel" should not be recited in claims. Finally, "biolistic" in line 2 is an adjective; --biolistics—is a noun.

In claim 3, line 3; claim 4, line 4; claim 5, line 4; "most effective" for what? This is a relative term for which no comparative basis is given.

Claims 7-25 do not further limit claim 1, since these claims recite limitations of claim 1 which are already present in claim 1.

The claims are generally narrative and indefinite, failing to conform to current U.S. practice. They appear to be a literal translation into English from a foreign document and are replete with grammatical and idiomatic errors.

Correction and/or clarification is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 1, 9 and 12 and all dependent claims are drawn to a method comprising pRT99GUS plasmid. The specification lacks sufficient evidence that the claimed biological material is either 1) reproducible, 2) known and readily available to the public, or 3) deposited in compliance with 37 CFR 1.801-1.809. If the claimed biological material was deposited under the provisions of the Budapest treaty, Applicant must provide a declaration stating that the claimed biological material was made under the provisions of the Budapest treaty in compliance with 37 CFR 1.801-1.809, and that all restrictions imposed by the depositor on the availability to the public of the deposited biological material will be irrevocably removed upon the grant of the patent. Applicant's attention is directed to 37 CFR §§1.801-1.809, MPEP §§ 2402-2411.05 and In re Lundak 773

F.2d 1216, 227 USPQ 90 (Fed. Cir. 1985) for further information concerning the Rules and Regulation for Deposit of Biological Materials for Patent Purposes.

If the deposit of these sequences is made under the terms of the Budapest Treaty, then an affidavit or declaration by the applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the DNA will be irrevocably and without restriction or condition released to the public upon the issuance of a patent would satisfy the deposit requirement made herein.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit, meets the criteria set forth in 37 CFR 1.801-1.809, applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number showing that

(a) during the pendency of the application, access to the invention will be afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the enforceable life of the patent, whichever is longer;

(d) the viability of the biological material at the time of deposit will be tested (see 37 CFR 1.807); and

(e) the deposit will be replaced if it should ever become inviable.

7. Claims 1-25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Enablement is considered in view of the *Wands* factors (MPEP 2164.01(a). The enablement issues are: all tea (*Camellia sinensis*), and all explants.

The breadth of the claims: The claims are drawn to "a novel combination of 360 parameters for the production of transgenic tea through biolostic" comprising a sequence of at least 19 steps reciting various positive steps, only one step of which is the combination of 360 parameters, and detailed information on the kinds of ranges, protocols, ranges which should function so as to produce transgenic tea. The claims are also drawn to all tea (*Camellia sinensis*) as well as to different cultivars Chinary, Cambod and Assamica, and different explants: leaf, sòmatic embryos, zygotic embryos and embryogenic callus from any source.

Guidance and Predictability: Applicant merely provides prophetic examples of a method of biolistics transformation of *Camellia sinensis* derived from various explants. *Camellia sinensis* is a recalcitrant plant for transformation and regeneration (specification, p. 2-3). While one working example may enable

a broader scope, Applicant has not provided even a single working example of biolistic transformation of *Camellia sinensis* using any specific explant. Applicant's prophetic examples lack any showing of exemplified transgenic *Camellia sinensis* plant material, plants, or progeny. Applicant does not disclose which tissue sources, in combination with which specific treatment protocols and selection conditions function as desired in the claimed invention. Applicant has provided no guidance on how to predictably eliminate inoperable embodiments from a virtually ad infinitum of possibilities other than by random trial and error, which is excessive experimentation and an undue burden.

Re "all explants": Plant transformation procedures employing plant tissue culture are unpredictable. The state of the art is that "plant transformation is an art because of the unique culture conditions required for each crop species. To accommodate a genotype or species that has not been manipulated in culture previously, one must either adapt an established protocol or create a new one." (Hansen et. al., 1999, Trends in plant Science, vol 4, pages 226-231, see page 230). Early attempts largely failed, due to failure to identify transformation-competent and regenerable cells. See, Potrykus, (Gene Transfer to Cereals: An Assessment, 1990, Biotechnology, 8(6): 535-542 p. 538, column 2, 3rd full ¶), which is written with an eye to cereals, but which is equally applicable to *Camellia sinensis*. Applicant does not disclose which tissue sources, in combination with which specific treatment protocol and selection conditions function as desired in the claimed invention. Applicant has provided no guidance on how to predictably eliminate inoperable embodiments from a virtually ad

infinitum of possibilities other than by random trial and error, which is excessive experimentation and an undue burden.

In view of the breadth of the claims (any *Camellia sinensis*, and any explant), the nature of the invention, the unpredictability of the art, the lack the lack of guidance in the specification, undue trial and error experimentations would be required to enable the invention as commensurate in scope with the claims.

Remarks

8. Claims 1-25 are free of the prior art of record, given the failure of the prior art of record to teach or reasonably suggest the production of transgenic tea by a biolistics process comprising the limitations of claim 1.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Georgia L. Helmer whose telephone number is 571-272-0976. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 571-272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Art Unit 1638
March 7, 2004

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